SUMMARY OF INTERVIEW

Attendees, Date and Type of Interview

The interview was conducted by telephone on 2/27/2008 and attended by Examiner Koharski and representatives for applicants, Andrew Douglas and Joshua Stowell.

Identification of Claims Discussed

The attendees discussed independent claims 1, 45 and 51.

Identification of Prior Art Discussed

The attendees discussed the prior art of record identified in the 12/28/07 Office Action.

Proposed Amendments

Applicants proposed the amendments to independent claims 1 and 51 embodied in this amendment.

Principal Arguments and Other Matters

Applicants distinguished the art of record based on the arguments now reflected in this amendment.

Results of Interview

Applicants agreed to submit the present amendment.

REMARKS/ARGUMENTS

Status of the Claims

In the Office Action, Claims 1-7, 9, 10, and 42-57 were rejected over the prior art as discussed below. In this Amendment, Claims 1, 45 and 51 have been amended and Claim 42 has been canceled. Claims 1-7, 9-10 and 43-57 remain pending for further consideration.

Indication of Consideration of Information Disclosure Statement

Applicants note that an Information Disclosure Statement was filed on April 27, 2007 and that the Office Actions mailed to-date do not reflect the Examiner's consideration of the references listed therein. Applicants request that the Examiner indicate in the next paper that this Statement has been considered.

Discussion of One Embodiment

This application ("'719 Application") describes an improved aspiration catheter that has a distal segment that enables, in one clinical application, ***aspiration of embolic material from a location within a filter*** (or other structure having a porous member) positioned within a blood vessel. In one technique described in the specification, a filter 18 is disposed along the distal end of a guidewire 16, which is positioned in a blood vessel downstream of an occlusion 12. The filter 18 captures emboli generated during a therapy, e.g., an angioplasty of the stenosis.

An aspiration catheter 30 as disclosed in this application is particularly well suited for aspirating emboli generated from such procedures, e.g., emboli captured in the filter 18. The aspiration catheter 30 has a guidewire lumen 36 (*see* Fig. 3 below) that can be used for advancement over the guidewire 16. A distal segment 42 of the catheter 30 extends distal of a distal port 46 of the guidewire lumen 36 to a distal aspiration port 40. The aspiration catheter 30 also has an aspiration lumen 34, which has a cross-sectional area that is significantly larger than the cross-sectional area of the guidewire lumen 36. *See* Fig. 3. The increased size of the aspiration lumen 34 relative to the size of the guidewire lumen 36 improves the performance of the catheter for a given vessel size.

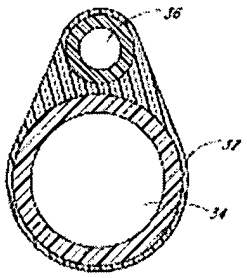

FIG. 3

As further illustrated in Figure 5C (shown below), the distal segment 42 can extend to within the filter 18 and can aspirate embolic material inside the filter. Thus, the catheter 30 can be used to remove emboli from a filter, which can help to sustain a patient through a procedure by enhancing flow downstream of the filter.

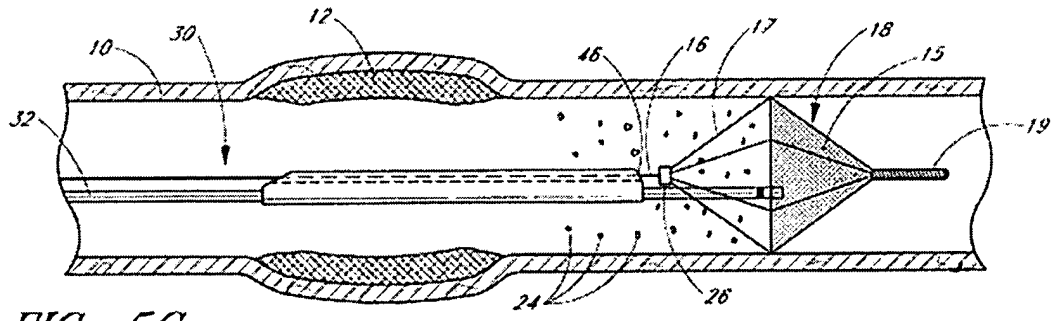

FIG. 5C

Objection to Claim 45

Applicants disagree with the objection to Claim 45. Applicants believe that the filter is referenced as a functional limitation throughout Claim 45. Claim 45 has been amended only to correct syntax. Applicants believe that the objection to Claim 45 should be withdrawn.

Rejection Based on Martin

In the Office Action under 35 U.S.C. § 102(b), Claims 1, 3, 4, 51 and 55 were rejected as being anticipated by U.S. Patent No. 5,405,341 issued to Martin (Martin). Further, Claims 2, 6, 7, and 43 were rejected under 35 U.S.C. § 103(a) as being obvious over Martin. *See* Office

Action at p. 5. Applicants do not agree with these rejections. However, to expedite allowance, amendments have been made to independent Claims 1 and 51 to further distinguish Martin.

Martin

Martin discloses a dual-lumen hemodialysis catheter designed to withdraw tainted blood from a vessel through an intake lumen and return cleansed blood to the vessel through a return lumen. Martin instructs that "the various forms of the invention can be used wherever dual flow is required." Martin at 1:14-15. Because Martin pertains to situations requiring dual flow, the lumens of the blood intake and blood return passages (28, 30) are in fluid communication with each other. Moreover, the blood intake and return passages are **necessarily equal in size** to provide balanced blood intake and return flows. This is illustrated in Figure 2 of Martin, reproduced below.

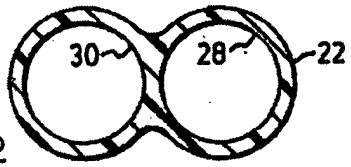

FIG. 2

Further, the blood return opening (46) in Martin is positioned downstream beyond the blood intake opening (44) to ensure that the cleansed blood does not mix with the tainted blood. *See* Fig. 4 (shown below); *Id.* at 3:34-43. Thus, Martin teaches removing blood only with the shorter blood intake passage (28) and not the longer blood return passage (30).

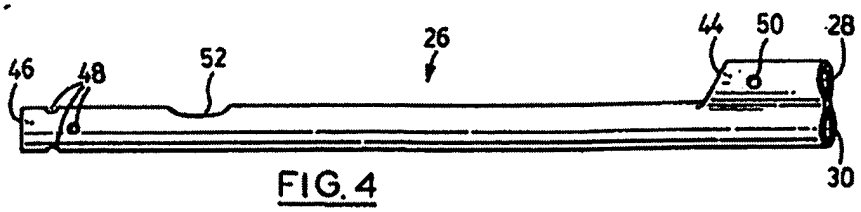

FIG. 4

In contrast to Martin, Claim 1 has been amended to recite an aspiration catheter, comprising:

> an elongate catheter body having proximal and distal ends;
>
> an aspiration lumen extending longitudinally through the elongate catheter body between the catheter body proximal end and an aspiration port at the catheter body distal end, the aspiration port being sized for aspirating particles from a blood vessel;
>
> a guidewire lumen being adapted for slidably receiving a guidewire and extending longitudinally through at least a portion of the elongate catheter body adjacent the aspiration lumen, from a proximal port to a distal port opening to the exterior of the elongate catheter body, the guidewire lumen having an inner cross-sectional area that is significantly smaller than the inner cross-sectional area of the aspiration lumen; and
>
> wherein the elongate catheter body includes a distal segment wherein the aspiration lumen extends distally beyond the distal port of the guidewire lumen, the aspiration lumen within the distal segment being configured to convey embolic material proximally from the blood vessel upon exposure to a source of negative pressure.

Unlike amended Claim 1, Martin requires the inner cross-sectional area of the intake and return lumens to be the same size. Also, Martin only describes removing blood for dialysis through the shorter lumen. Accordingly, Martin does not teach all of the limitations of amended Claim 1.

Similarly, Claim 51 has been amended to recite an aspiration catheter system for aspirating embolic material from a filter positioned within a blood vessel, comprising:

> an elongate catheter body having proximal segment and a distal segment;
>
> an aspiration lumen extending longitudinally through the elongate catheter body between the catheter body proximal segment and an aspiration port at a distal end of the the catheter body distal segment, the aspiration port being sized for aspirating particles from a blood vessel;
>
> a guidewire lumen being adapted for slidably receiving a guidewire, the guidewire lumen and extending longitudinally through the elongate catheter body adjacent the aspiration lumen, from a proximal port to a distal port, the guidewire lumen further having an inner cross-sectional area that is significantly smaller than the inner cross-sectional area of the aspiration lumen; and
>
> a source of negative pressure in fluid communication with the aspiration lumen to facilitate aspiration of emboli from the blood vessel;

wherein the aspiration lumen is not in fluid communication with the guidewire lumen.

Martin does not describe all of the limitations of Claim 51.

Thus, for at least the reasons set forth above, Martin does not anticipate amended Claims 1 and 51. Claims 2-4, 6-7, 43 and 55 depend from Claim 1 or 51 and further define the invention thereof. Accordingly, these claims are allowable for the same reasons that Claims 1 and 51 are allowable and are allowable in their own right. Applicants request that the rejection of Claims 1-4, 6-7, 43, 51 and 55 be withdrawn and these claims be allowed.

Rejection Based on Melker

Claims 1, 3, 51, and 55 were rejected as being anticipated by U.S. Patent No. 5,328,480 issued to Melker et al. (Melker). Further, Claims 2, 6, 7, and 43 were rejected under 35 U.S.C. § 103(a) as being obvious over Melker. *See* Office Action at p. 5. Applicants do not agree with these rejections. However, to expedite allowance, Claims 1 and 51 have been amended to further distinguish Melker.

Melker

Melker discloses a multi-lumen wire guide introducer and method of positioning a wire guide in the introducer prior to insertion of the introducer and wire guide into a vessel of the vascular system. Melker at 1:14-19. Melker further discloses that the introducer comprises a hollow cannula such as a hypodermic needle having a flash back chamber positioned in the first lumen for introducing the needle and tubular member into the blood vessel of the patient. *Id.* at 2:36-40. The introducer disclosed by Melker is approximately 10 cm in length. *Id.* at 4:15-17.

Unlike amended Claims 1 and 51, Melker does not disclose an aspiration lumen with an aspiration port being sized for aspirating particles from a blood vessel. In fact, Melker does not describe aspiration as a possible application of the multi-lumen wire guide introducer. Further, the flashback chamber strongly suggests that the introducer is not used with a source of negative pressure because the flashback chamber fills when a distal end of the lumen is exposed to positive pressure in a blood vessel.

Moreover, Melker discloses that the cross-sectional diameter of the guidewire lumen (15) is ***larger than*** the cross-sectional diameter of the first lumen (14) sized to accommodate a hypodermic needle. *See e.g.*, Fig. 2 (shown below); *Id.* at 4:15-19.

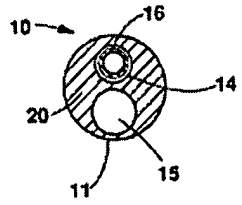

Fig. 2

Thus, Melker does not disclose the limitations of amended Claims 1 and 51, where the guidewire has an inner cross-sectional area that is significantly smaller than the inner cross-sectional area of the aspiration lumen.

Thus, for at least the reasons set forth above, Melker does not describe all of the limitations of amended Claims 1 and 51. Claims 2-3, 6-7, 43 and 55 depend from Claim 1 or 51 and further define the invention thereof. Accordingly, these claims are allowable for the same reasons that Claims 1 and 51 are allowable and are allowable in their own right. For this reason, Applicants request that the rejection of Claims 1-3, 6-7, 43, 51 and 55 be withdrawn and these claims be allowed.

Rejection based on Bagaoisan

Claims 1, 44, and 51-53 were rejected as being anticipated by U.S. Patent No. 6,152,909 issued to Bagaoisan et al. (Bagaosian). In particular, Figures 1-4 of Bagaoisan were the basis for the anticipation rejection. *See* Office Action at p. 4. Further, Claims 2, 6, 7, and 43 were rejected under 35 U.S.C. § 103(a) as being obvious over Bagaoisan. *See* Office Action at p. 5. Applicants do not agree with these rejections. However, to expedite allowance, Claims 1 and 51 have been amended to further distinguish Bagaoisan.

Bagaoisan

Bagaoisan discloses an aspiration catheter for aspirating emboli from the vasculature of a patient. Bagaoisan at 1:16-18. In connection with the embodiment of Figures 1-4, the aspiration catheter is advanced over a guidewire which is placed in the aspiration lumen. In particular, the

proximal end of the guidewire is inserted into the distal end of the aspiration catheter 10 and the aspiration catheter is slidably advanced over the guidewire. *Id.* at 8:36-41.

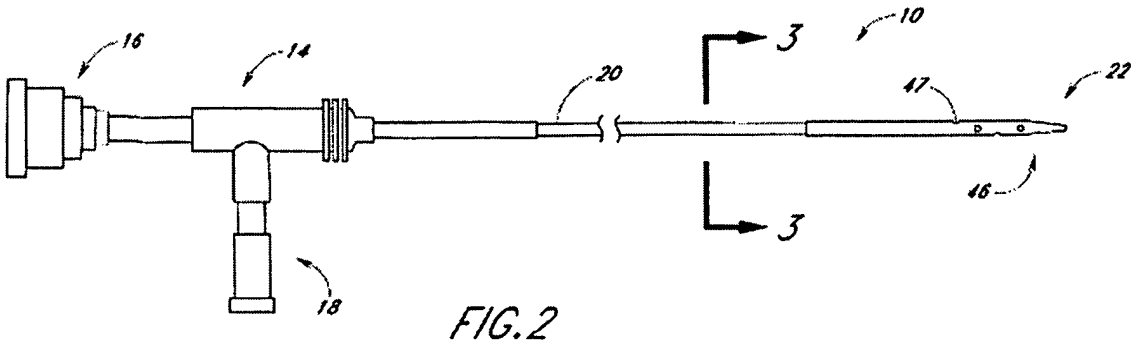

FIG. 2

As Figure 4 shows, the guidewire 26 is disposed in the aspiration catheter tubular body 20 of the aspiration catheter 10.

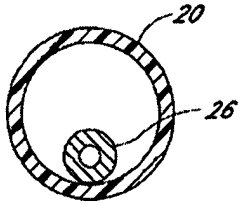

FIG. 4

Similar to Martin and Melker, Bagaoisian does not disclose in connection with Figures 1-4 a shorter, smaller guidewire lumen and a longer, larger aspiration lumen. Further, Bagaoisian also does not describe in connection with Figures 1-4 a distal segment wherein the aspiration lumen extends distally beyond the distal port of the guidewire lumen.

The embodiment of Figure 13 in Bagaoisan (shown below) was discussed in the interview summarized above. In this embodiment, the guidewire lumen 214 extends distally beyond the aspiration lumen 212.

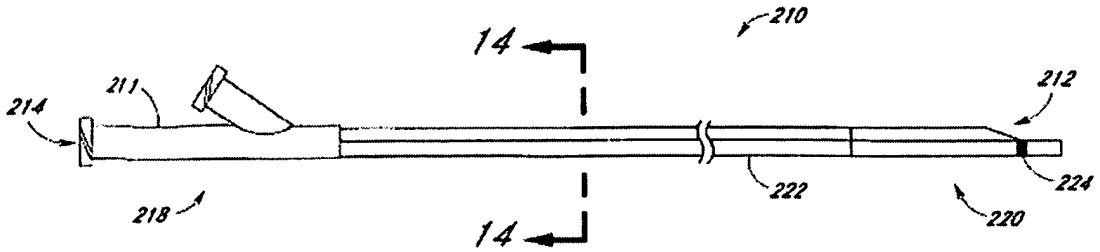

FIG. 13

Figure 14 (which is inverted relative to Figure 13) shows that in the embodiment of Figure 13, the guidewire lumen 214 has a smaller cross-sectional area than the aspiration lumen 212. *Id.* at 8:33-36; 8:59-62.

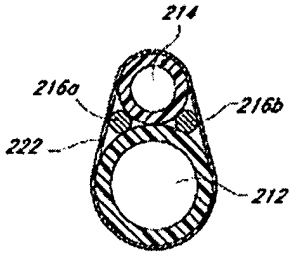

FIG. 14

Thus, for at least the reasons set forth above, Bagaoisian does not describe all the limitations of amended Claims 1 or 51. Claims 2, 6-7, 43-44 and 52-53 depend from Claims 1 and 51 and further define the invention thereof. Accordingly, these claims are allowable for the same reasons that Claims 1 and 51 are allowable and are allowable in their own right. For this reason, Applicants request that the rejection of Claims 1-2, 6-7, 43-44, and 51-53 be withdrawn and these claims be allowed.

Additional Rejections Under 35 U.S.C. § 103

Claims 5, 42, and 53-55 were rejected as being obvious over Martin in view of Bagaoisian and Claims 9-10, 45-50, 56, and 57 were rejected as being obvious over Bagaoisian in view of U.S. Patent No. 6,168,579 issued to Tsugita (Tsugita).

Martin in view of Bagaoisian

Claims 5 and 42 depend from amended Claim 1 and further define the invention thereof. As discussed above, neither Martin nor Bagaoisian disclose, for example, a device where an aspiration lumen extends distally beyond a distal port of a guidewire lumen and where the guidewire lumen has an inner cross-sectional area that is significantly smaller than an inner cross-sectional area of the aspiration lumen. Where neither reference discloses these features of applicants' invention, their combination cannot do so. Accordingly, for at least this reason, combining the references does not render the invention of Claim 1 obvious. Applicants request that the rejection of Claims 5 and 42 be withdrawn and these claims be allowed.

Similarly, Claims 53-55 depend from amended Claim 51 and further define the invention thereof. Also as discussed above, neither Martin nor Bagaoisian discloses an aspiration lumen extending longitudinally through an elongate catheter body between a catheter body proximal segment and an aspiration port at a distal end of a catheter body distal segment and where the guidewire lumen has an inner cross-sectional area that is significantly smaller than an inner cross-sectional area of the aspiration lumen. Accordingly, for at least this reason, combining the references does not render the invention of Claim 51 obvious. Applicants request that the rejection of Claims 53-55 be withdrawn and these claims be allowed.

Bagaoisian in view of Tsugita

Bagaoisian has been discussed above. Tsugita is asserted only to add an irrigation lumen, therapy device and porous filter attached to the distal end of the guidewire. For at least the reasons discussed above, the combination of Bagaoisian and Tsugita would not teach or suggest all of the limitations of independent Claims 1, 45 and 51, and Applicants request that the rejection of Claims 9-10, 45-50, 56, and 57 be withdrawn and these claims be allowed.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicants reserve the right to pursue at a later date any previously pending or other

broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

Conclusion

For the foregoing reasons, Applicants believe all the pending claims are in condition for allowance and should be passed to issue. Furthermore, any remarks in support of patentability of one claim should not be imputed to any other claim, even if similar terminology is used. Any remarks referring to only a portion of a claim should not be understood to base patentability on that portion or that the limitation discussed is essential or critical; rather, patentability must rest on each claim taken as a whole. Applicants respectfully traverse each of Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches, even if not expressly discussed herein. Although changes to the Claims 1, 45 and 51 have been made, no acquiescence, disclaimer or estoppel is intended or should be implied thereby; such amendments are made only to expedite prosecution of the present application and are without prejudice to the presentation or assertion, in the future, of claims relating to the same or similar subject matter.

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call Applicants' attorney, Andrew M. Douglas at (949) 721-7623 to resolve such issue(s) promptly.

The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525.

Respectfully submitted,
/James F. Crittenden/
Registration No. 39,560
Agent for Applicants

Medtronic Vascular, Inc.
3576 Unocal Place
Santa Rosa, CA 95403
Facsimile No.: (707) 543-5420